



PARK DENTAL
RESEARCH CORPORATION
NEW YORK, NY

K121707

SEP 24 2012

510(k) Summary

Submitter: Owner - Park Dental Research Corporation, 2401N. Commerce, Ardmore, OK. Office 212.736.3765, Fax 214.233.7279. Point of Contact - Ron Bulard. Submitted 5/18/2012

Proprietary Name: LEW Mini O-Ball Implant

Common/Usual Name : Implants, endosseous implants, MDI's, Mini-implants, SDI's, Small diameter implants

Classification Name and Number : Endosseous Dental Implant (21 CFR 872.3640 DZE)

Devices for Substantial Equivalence: IMTEC MDI K031106, IMTEC MII K081653, Intra-Lock MDL K070601, Intra-Lock MILO K050970, Prizmatic Inclusive K100932

Device Description

The LEW Mini O-ball implant (MDI) is available with a 1.5 mm gingival collar in three diameters: 2.0mm, 2.5mm, and 3.0mm. The LEW Mini O-ball implant (MDI) is also available without a gingival collar in two diameters; 2.0mm and 2.5mm. The implant is made of Titanium alloy (Ti6Al4V ELI per ASTM F 136-02). The thread surface is ablated with 50 micron aluminum oxide to remove shiny machined surface. The LEW Mini O-ball implant (MDI) is available in thread lengths ranging from 10mm to 18mm allowing for maximum bone engagement. The system consists of the major component, a root-form, screw type, self-tapping implant, and accessories designed to facilitate placing and using the implant. The accessories contact tissues for less than 1 hour and therefore are exempt from 510(k) requirements are described generally but are of course subject to general controls and are covered by the Quality System documents.

Indications for Use

The Park Dental Research Corporation's LEW O-ball implant system is a self-tapping titanium threaded screw indicated for long-term intra-bony applications. Additionally, the LEW Mini O-ball Implant may be used for inter-radicular transitional applications.

These devices will permit immediate splinting stability and long-term fixation of new or existing crown and bridge installations, for full or partial edentulism, and employing minimally invasive surgical intervention.

The 2.0mm , 2.5 mm, and 3.0 mm diameter are intended to support single or multi-unit restorations in both long-term and temporary applications throughout the maxillary and mandibular arches.

Testing

Fatigue testing was conducted according to ISO 14801 on both models of 2.0mm implant.

Compliance with Performance Standards: No performance standards are applicable, however we followed "Class II Special Controls Guidance - Document: Root-form Endosseous Implants and Endosseous Dental Implant Abutments" issued May 12, 2004. The Ti6Al4V-ELI titanium used in these implants meet ASTM F-136 "Standard Specifications for Wrought Titanium-6aluminum-4Vanadium Allow for Surgical Implant Applications"

Substantial Equivalence

Summary : The LEW Mini O-Ball implant system is substantially equivalent to several small diameter implants systems currently on the market. We have listed five 510(k) implants systems. A detailed chart of more implant systems is included in Section 12

| Element of Comparison | LEW Mini O-Ball Implant | IMTEC K031106 | IMTEC K081653 | Intra-Lock K070601 | Intra-Lock K050970 | Prismatic K100932 |
|-----------------------|--|--|---|---|---|--|
| Diameter (mm) | 2.0, 2.5, 3.0 | 1.8, 2.1, 2.4 | 2.9 | 2.0, 2.5 | 3.0 | 2.2, 2.5, 3.25 |
| Length (mm) | 10,13,15,17,18 | 10,13,15,18 | 10,13,15,18 | 10,11.5,13,15,18 | 10,11.5,13,15,18 | 10, 13, 15 |
| Implant head shape | O-ball Connection compatible/SE to IMTEC K031106 and Intra-Lock K070601. SE | O-ball Connection compatible to an o-ring metal housing | O-ball Connection compatible to an o-ring metal housing | O-ball Connection compatible/SE to IMTEC K031106 | O-ball Connection compatible/SE to IMTEC K031106 | O-Ball Connection SE to IMTEC K031106 |
| Indications for use | The Park Dental Research Corporation's LEW O-ball implant system is a self-tapping titanium threaded screw indicated for long-term intra-bony applications. Additionally, the LEW Mini O-ball Implant may be used for inter-radicular transitional applications. These devices will permit immediate splinting stability and long-term fixation of new or existing crown and bridge installations, for full or partial edentulism, and employing minimally invasive surgical intervention. The 2.0mm, 2.5 mm, and 3.0 mm diameter are intended to support single or multi-unit restorations in both long-term and temporary applications | The MDI and MDI Plus are self-tapping titanium threaded screws indicated for long-term intra-bony applications. Additionally, the MDI may be used for inter-radicular transitional applications. These devices will permit immediate splinting stability and long-term fixation of new or existing crown and bridge installations, for full or partial edentulism, and employing minimally invasive surgical intervention. | The MII Implant is intended to support single or multi-unit restorations in both long-term and temporary applications throughout the maxillary and mandibular arches. The MII implant is indicated for immediate loading when good primary stability is achieved. Additionally, this device will permit stability and long term fixation of upper and lower dentures in edentulous cases. | 3. Mini Drive-Lock™ Dental Implants are intended for use as a self-tapping titanium screw for transitional or intra-bony long-term applications. 4. Mini Drive-Lock™ Dental Implants are indicated for long-term maxillary and mandibular tissue supported denture stabilization. Multiple implants should be used and may be restored after a period of time or placed in immediate function. | MILO™ Implants are indicated for long-term maxillary and mandibular tissue-supported denture stabilization. Multiple implants may be restored after a period of time or placed in immediate function. | Inclusive® Mini Implants are self-tapping threaded titanium screws indicated for long-term applications. Inclusive® Mini Implants may also be used for provisional applications. These devices will allow immediate loading and long-term stabilization of dentures and provisional stabilization of dentures while standard implants heal. To be used for immediate loading only in the presence of primary stability and appropriate occlusal loading. |

| Element of Comparison | LEW Mini O-Ball Implant | IMTEC K031106 | IMTEC K081653 | Intra-Lock K070601 | Intra-Lock K050970 | Prismatic K100932 |
|-------------------------------|---|---|--|---|---|---|
| | throughout the maxillary and mandibular arches. | | | | | |
| Material | Ti6Al4V ASTM F-136 | Ti6Al4V ASTM F-136 | Ti6Al4V ASTM F-136 | Ti6Al4V ASTM F-136 | Ti6Al4V ASTM F-136 | Ti6Al4V ASTM F-136 |
| Sterilization | Delivered sterile | Delivered sterile | Delivered sterile | Delivered sterile | Delivered sterile | Delivered sterile |
| Packaging | Vial in a pouch | Vial in a pouch | Vial in a pouch | Vial in a pouch | Vial in a pouch | |
| Product Code | dze | dze | dze | dze | dze | dze |
| Screw pitch & depth of thread | Thread pitch ranges between IMTEC's fine and coarse pitch as well as thread depth | Fine thread pitch for 1.8,2.1 Diameters. Ccoarser pitch for 2.4 | Coarse Pitch and depth | Thread pitch ranges between IMTEC's fine and coarse pitch as well as thread depth | Coarse Pitch and depth | Coarse Pitch and depth |
| Bone Contact Surface | Blasted and clean (SLA equivalent), machined surface, SE to IMTEC K031106 | Blasted and clean (SLA equivalent), machined surface | Blasted and clean (SLA equivalent), machined surface | Blasted and clean, , SE to IMTEC K031106, In addiion with embedded CaPhos molecules | Blasted and clean, , SE to IMTEC K031106, In addiion with embedded CaPhos molecules | Blasted Etched Surface, SE to IMTEC K031106 |
| Driver Connection | Square 1.65mm SE to IMTEC K031106 | Square 1.65mm | Square 1.65mm | Square 1.65mm SE to IMTEC K031106 | Square 1.65mm SE to IMTEC K031106 | Square 1.65mm SE to IMTEC K031106 |
| Included Prosthetic | Metal Housing(s) with o-ring, SE to IMTEC K031106 | Metal Housing(s) with o-ring, | Metal Housing(s) with o-ring, | Metal Housing(s) with o-ring, SE to IMTEC K031106 | Metal Housing(s) with o-ring, SE to IMTEC K031106 | Metal Housing(s) with o-ring, SE to IMTEC K031106 |
| Fatigue testing | Tested to ISO 14801 (results attached) . The LEW Mini O-Ball implant is substantially equivalent <i>or stronger*</i> than IMTEC's K031106 MDI implant. The same titanium alloy, a SE of thread pitch, form and depth, a SE of threaded lengths. <i>*The IMTEC MDI 1.8mm diameter is approved, when calculated has a lower fatigue properties than a SE 2.0mm diameter implant</i> | In clinical use since 1998 | In clinical use since 2008 | SE to IMTEC K031106 | SE to IMTEC K081653 | SE to IMTEC K031106 |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Park Dental Research Corporation
Mr. Ronald Bulard
President
2401 North Commerce Street, Suite B
Ardmore, Oklahoma 73401

SEP 24 2012

Re: K121707
Trade/Device Name: Lew Mini O-Ball Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: August 27, 2012
Received: September 4, 2012

Dear Mr. Bulard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

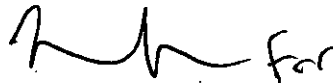
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'A. Watson for'.

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121707

Device Name: LEW Mini O-Ball Implant

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Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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